

Avatar trial protocol
-Amendment to surgical delays-

Aortic Valve Replacement Versus Conservative Treatment in
Asymptomatic Severe Aortic Stenosis (AVATAR trial)

NCT number : NCT02436655.

Date of amendment: 04.01.2021

Amendmen to statystical analysis

1. Patients randomized to AVR surgery who received delayed surgery (more than 8 weeks after randomization) due to COVID -19 public health emergency will be documented and this delay will be defined as an anticipated minor deviation from the clinical protocol
2. Appropriate statistical procedures will be performed and results will be published according to the FDA guidance "Conduct of Clinical Trials of Medical Products During the COVID-19 Public Health Emergency Guidance for Industry, investigators, and Institutional Review Boards"